510(k) Summary

MEDTRONIC Sofamor Danek
ATLANTIS® Anterior Cervical Plate System
March 8, 2013

JUN 0 4 2013

I. **Company:**

Medtronic Sofamor Danek, USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133

II. **Contact:**

Kristi Frisch
Regulatory Affairs Specialist
Telephone: (901) 399-2221
Fax: (901) 346-9738

III. **Proposed Proprietary Trade Name:**

ATLANTIS® Anterior Cervical Plate System

IV. **Classification Names:**

Spinal Intervertebral Body Fixation Orthosis

Class:

II

Product Code:

KWQ (21 CFR 888.3060)

V. **Description:**

The ATLANTIS® Anterior Cervical Plate System is intended for the anterior screw fixation from C2 to T1 in the cervical spine. The device is manufactured from titanium alloy. Stainless steel and titanium implant components must not be used together in a construct.

The ATLANTIS® Anterior Cervical Plate System consists of plates of various lengths and screws. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The ATLANTIS® Anterior Cervical Plate System is to be used with cleared cervical supplemental instrumentation.

VI. Indications for Use:

The ATLANTIS® Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2-T1 in the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis, 5) pseudoathrosis, and/or 6) failed previous fusions.

NOTA BENE: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

VII. Summary of the Technological Characteristics:

The purpose of this 510(k) submission is to seek clearance for subject parts which are provided sterile.

VIII. Identification of Legally Marketed Devices:

The design features and indications for use for the sterile subject are substantially equivalent to the predicate ATLANTIS® Anterior Cervical Plate System (K021461, S.E. 07/22/2002 and K081038, S.E. 08/15/2008)

IX. Discussion of Non-Clinical Testing:

Sterilization assessments were completed for the sterile subject plates and screws. These reports provide adequate evidence for the validated sterilization parameters. Shelf life rationales show sterile subject device package integrity with an eight year shelf life.

X. Conclusion:

Based on the sterilization and packaging rationales and other supporting documentation provided in this pre-market notification, Medtronic believes that the sterile subject device demonstrates substantial equivalence to the listed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2013

Medtronic Sofamor Danek USA, Incorporated
% Ms. Kristi Frisch
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K130640
Trade/Device Name: ATLANTIS® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 5, 2013
Received: April 8, 2013

Dear Ms. Frisch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: ATLANTIS® Anterior Cervical Plate System

Indications for Use:

The ATLANTIS ® Anterior Cervical plate system is intended for anterior interbody screw fixation from C2 to T1 in the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis, 5) pseudoathrosis, and/or 6) failed previous fusions.

Nota Bene: This device system is intended for anterior cervical intervertebral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices